

Remarks

Applicant would like to thank the Examiner for the very useful telephone interview held October 14, 2003.

Claims 1-12, 14-32, 35, 39, 41, 42, 45, and 46 are pending in the above-referenced application. The Examiner has rejected claims 1-12, 14-32, 35, 39, 41, 42, 45, and 46. Claims 1, 5, 12, 14, 17, 18, 39, 41, 42, 44, and 46 have been amended, and new claims 47-52 have been added. Support for claims 47-48 reciting ethanol as the endosomal lysing agent can be found on page 7, lines 22-24. Support for claim 48 reciting ortho-esters can be found on page 8, starting at line 10. Support for claim 49-50 reciting hydrazone and cis-acetonyls can be found on page 9, line 14. Support for claim 52 reciting imidazole as the ionizable functional group can be found on page 9, lines 29-33. Applicant respectfully submits that no new matter is presented with these amendments and additional claims. Applicant specifically intends the claimed subject matter to encompass equivalents of the claimed invention notwithstanding that such equivalents may no longer be literally encompassed by the claim language. Applicant reserves the right to prosecute without prejudice in a future application subject matter amended from the claims by the Amendment submitted herewith. Applicant respectfully requests consideration of the amended claims presented herein and respectfully submits that the pending claims are now in condition for allowance.

I. Rejection under 35 U.S.C. § 112, first paragraph, for lack of written description.

The Examiner has rejected claims 1-12, 14-32, 35, 39, 41, 42, and 45 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner maintains that the specification only provides sufficient written description of two classes of endosomolytic polymers. The first class includes polymers comprising hydrolyzable functional moieties selected from the group consisting of ortho-esters, hydrazones, and cis-acetonyls that release an endosomal lysing agent such as ethanol upon hydrolysis. The second class includes polymers comprising hydrolyzable functional moieties selected from the group consisting of ortho-esters, hydrazones, and cis-acetonyls; plus ionizable functional moieties comprising proton acceptor

sites. Although Applicant disagrees that the specification only provides support for these two classes of polymers, Applicant has amended the base claims to recite these two classes of polymers, both of which the Examiner has indicated are supported by the specification, for the purposes of securing allowance of the present application. Support for the polymer comprising a hydrolyzable functional moiety capable of releasing an endosomal lysing agent such as ethanol upon hydrolysis can be found at page 7, lines 16-24 and in Figure 2. Support for the polymers including ionizable functional groups can be found at page 7, lines 25-30, and in Figure 4. Therefore, Applicant submits that the amended claims find written description support in the specification as filed and requests that the rejection be removed.

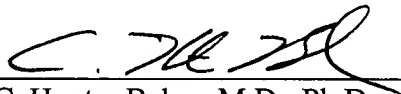
II. Rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner has rejected claims 1-12, 14-32, 35, 39, 41, 42, 45, and 46 under 35 U.S.C. § 112, first paragraph, for lack of enablement. As above, the Examiner maintains that the claimed invention is only enabled for two particular classes of endosomal lysing polymers. Examples of making and using the claimed polymers start on page 20 of the specification, and Figures 1-5 further support the claims. Applicant submits that the amended claims are enabled by the specification for the full scope of the claims as indicated by the Examiner. Applicant, therefore, requests that the rejection be removed.

III. Rejection under 35 U.S.C. § 103, as being unpatentable over Pack *et al.* (US 2001/0006817) taken with Thorpe (U.S. Patent 5,762,918). Claims 1-12, 14-32, 35, 39, 41, 42, and 45 stand rejected under 35 U.S.C. § 103, as being unpatentable over Pack *et al.* (US 2001/0006817) taken with Thorpe (U.S. Patent 5,762,918). In order to remove US 2001/0006817 from consideration by the Examiner as not having been invented by another, Applicant has submitted a Declaration under 37 C.F.R. § 1.132 by Robert S. Langer stating that the claimed invention was not invented by another. Applicant requests that the rejection be removed since the material disclosed in the published patent was not invented by another and, therefore, can not be used to render obvious the claimed invention in the present application. Without Pack *et al.*, the *prima facie* case of obviousness has not been made because as the Examiner admits “Pack *et al.* teaches a cell delivery composition comprising a polymeric carrier,

which comprises an endosomolytic polymer having ionizable functional moieties or monomers, and a biological active agent” Therefore, Applicant requests that the rejection be removed.

If it is believed that a telephone conversation would expedite matters, the Examiner is invited to contact the undersigned at (617) 248-5215. Although it is believed that there is no fee associated with this amendment, if Applicant is mistaken, please charge any fees to our Deposit Account Number: 03-1721.

Respectfully Submitted,


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December 2, 2003

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